

REMARKS

I. Clarification

The paragraph bridging pages 3 and 4 of the Response filed

November 18, 2009, states:

That unpredictability is further evidenced after the initial observations of Pagel, where renal effects of levosimendan were studied in animals suffering from renal failure. See, e.g., Oldner et al., "Effects of levosimendan, a novel inotropic calcium-sensitizing drug, in experimental septic shock," *Crit. Care Med.*, 29(11):2185-2193 (2001) ("Oldner"). In Oldner, experimental septic shock (sepsis) was induced in pigs, causing, among other symptoms, acute renal failure. However, levosimendan failed to affect the endotoxin-induced reduction in renal blood flow. See Oldner at Abstract; page 2185, right col., first full paragraph; Figure 3 (Qrai - renal blood flow index); and page 2191, right col., first full paragraph. Accordingly, Oldner actually teaches away from the present invention, as levosimendan exhibited no beneficial renal effects in the renal failure model.

In an abundance of caution, Applicants wish to clarify that Oldner, not Pagel, studied renal effects of levosimendan in animals suffering from renal failure. In contrast to Oldner, Pagel studied the renal effects of levosimendan in **healthy** dogs.

II. Conclusion


In view of the foregoing additional remarks, Applicants respectfully request reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this Supplemental Response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

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By: 
Kimberly D. Smith
Reg. No. 63,219
(202) 408-4000